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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,174	04/24/2000	GARRIT-JAN BOUDEWIJN VAN OMMEN	294-78	9590

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 06/03/2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/445,174

Applicant(s)

VAN OMMEN ET AL.

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 28 April 2002.

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 15-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 15-55 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

4) ☐ Interview Summary (PTO-413) Paper No(s) _____

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other:

DETAILED ACTION

Status

1. The finality of the previous office action is withdrawn and the current, non-final action is applied to the claims as submitted in the Amendment filed April 29, 2002.

Claim Rejections - 35 USC § 112 – First paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 15-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification. In particular two very large

genus elements are claimed. The first genus is the genus of all probes which have certain detection capacities. The second genus is the genus of all deletions of exon 13 or exon 22 of BRCA1. These genus includes variants for which no written description is provided in the specification. These two large genus are represented in the specification by only the particularly named SEQ ID Nos. Thus, applicant has express possession of only two particular deletions in BRCA1 in exon 13 and exon 22, and only a few particular probes, in a genus which comprises hundreds of millions of different possibilities. Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains, whether for the probes or for the deletions. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided. Further, these claims encompass alternately spliced versions of the proteins, allelic variants including insertions and mutations, inactive precursor proteins which have a removable amino terminal end, and only specific amino acid sequences have been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

"A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169-

71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the deletions from exon 13 and exon 22 lack any specific structure, is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the two specific deletions, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim to "a major part of exon 13", for example.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound solely by its functional utility, as a deletion, without any definition of the particular deletions claimed. Here, the probes for example are defined solely by their functional ability to detect a deletion and lack any definition not tied to this functional utility.

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise deletions of the BRCA1 gene in exon 13 or 22.. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Claim Rejections - 35 USC § 112

4. Claims 15-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite what are the metes and bounds of claims 15-55 due to the use of the phrase "means is provided for" in claim 15. Specifically, while this issue was previously addressed in prosecution, it was not clarified if the term was intended to invoke the requirements of 112, sixth paragraph "means plus function" language or if sufficient structure is asserted to be present to avoid 112, sixth paragraph. In particular, the response filed June 11, 2001 states "The specification is replete with examples of the use of "a means" for detecting deletions of a stretch of nucleotides from a BRCA1 gene" and cites page 6, lines

3-15. This citation is to generic means which would not support means plus function language. However, the current language appears to implicate 112, sixth paragraph. Therefore, all appropriate rejections will be made, as if the claims are not limited by the "means plus function" language since the claims are unclear on this limitation.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 15-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Miki et al (Science (1994) 266:66-71).

Miki teaches PCR primers to amplify every exon of BRCA1 including exons 13 and 22 (page 71, footnote 26 states that primers for every exon are available publicly upon request). These primers would inherently function in a diagnostic test to detect deletions, and in particular large deletions, of exons 13 and 22 because the resultant PCR products would differ in size from the PCR products of controls without deletions. Further, Miki teaches the resultant PCR products (page 71, footnote 26) which PCR products would inherently function as hybridization probes for detection of exons 13 and 22 which PCR products would comprise a sequence complementary to both sides of the deletion. Miki teaches

the elements necessary for southern and northern blotting (page 69, figures 3 and 4).

Response to Arguments

7. Applicant's arguments filed April 29, 2002 have been fully considered but they are not persuasive.

Applicant argues, incorrectly, that the rejection is based upon 112, second paragraph. The rejection previously made, which is also made in this non-final action, though in slightly different form, is based upon the 35 U.S.C. 112, first paragraph written description requirement.


As noted in the rejection, the description by function is inadequate to comply with the written description requirement. Applicant's amendment improves the claim, by removing elements which are clearly not supported by the specification, but retains claims which are drawn to broad embodiments claimed by function and for which no concomitant structure is provided. For example, a claim to a probe which detects a deletion of a major part of exon 13 has two separate functional elements without structure. First, the probe is entirely functional since no structure for the probe is provided. Second, the deletion itself is functional, since no particular deletion structure, other than the one deletion in exon 13, is exemplified. Thus, applicant does not have possession of any other deletion in exon 13, nor does application have possession of any probe to detect any deletion in exon 13. Therefore, this rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman
Primary Examiner
Art Unit 1637

May 28, 2002